EXHIBITS 1–2 TO DECLARATION OF AMY WALSH

EXHIBIT 1

Case 5:18-cr-00258-EJD Document 1396-3 Filed 04/08/22 Page 3 of 91

To: 'Cook, Stephen D MAJ MIL USA USASOC'[stephen.d.cook@us.army.mil]

Cc: Elizabeth Holmes[eholmes@theranos.com]

From: Daniel Edlin

Sent: Thur 1/19/2012 7:28:23 AM

Importance: Normal

Subject: RE: Lab Set (UNCLASSIFIED)
Received: Thur 1/19/2012 7:28:24 AM

Theranos USASOC Project CONFIDENTIAL - DO NOT CIRCULATE.PDF

Major Cook,

Thank you for the clarification and for outlining your proposal in detail. We understand your request and will provide you with follow up to confirm the testing feasibility and time lines you suggested below. In order that we may fully evaluate your inquiry, if you would, please provide a comprehensive list of all of the assays you plan to test.

Additionally, please see attached an overview of the Theranos - USASOC project and background information on Theranos. Given that the attached file is not encrypted and is highly confidential, we kindly ask that the disclosure and circulation be limited accordingly (military use only).

Thank you and please let us know if you have any questions. We very much look forward to working with you on this project.

Best regards,

Dan

----Original Message-----

From: Cook, Stephen D MAJ MIL USA USASOC [mailto:stephen.d.cook@us.army.mil]

Sent: Tuesday, January 17, 2012 5:49 AM

To: Daniel Edlin

Cc: Elizabeth Holmes; michael.mcginnis@us.army.mil

Subject: RE: Lab Set (UNCLASSIFIED)

UNCLASSIFIED

Dan,

Actually my verbal requests of last week changed from my written inquiry that you answered below. As you know, we're looking to evaluate your system to determine its utility across the operations and environments in which we'd like to deploy it. In order to do so we'd like to conduct an assessment period after which we'd likely move forward with a 12 month renewable service contract that is more in-line with your current billing system.

In the absence of background materials, I am proposing an evaluation period that looks like this:

3ea devices (GPS disabled) - running up to 400 assays each per month (base deficit, international normalized ratio, hematocrit, hemoglobin, complete blood count, and chem 7) from 01MAR through 31MAY12. The 3ea units will be assessed for performance of core function as well as operation from various mobility platforms (aircraft, ground vehicles, etc) as well as various environmental conditions.

If the above is successful, deliver 7ea additional devices (GPS disabled) - for a total of 10ea devices from 01JUN through 31AUG12. The original 3ea devices will likely continue to run up to 400 assays each per month. The 7ea devices will likely run up to 100 assays per month and be used across the globe to determine deployability.

We would like to accomplish the above with a firm-fixed price contract totalling \$75K that includes assays as mentioned (even if less are performed) and shipping costs. We can distribute the funds between the two phases as \$18K/\$57K - or any ratio that makes sense from a Theranos standpoint.

We'd be looking at 2ea contract CLIN's of "Assessment Period 1" and "Assessment Period 2" (OPTION). Upon conclusion of "Period 1", our service contract representative would likely begin work with you to determine terms of contract to facilitate seamless transition of all 10ea devices upon successful performance of "Period 2". Likely that 8ea devices would be active at any given time with 2ea devices retained as spares to employ as required.

Please provide your input on the above. If you concur, we'd like to discuss in further detail and move to a quote and

contract at the earliest opportunity.
Thank you.
Regards,
Steve
Stephen Cook
MAJ, SF
APM Soldier Systems
(comm.)
"I am not a Contracting Officer, I cannot direct work or initiate or modify contracts; I do not have the authority to commit the Government financially in any way. If the Government desires to alter your requirements as a result of the information obtained from this email discussion, changes will be issued in writing and signed by the appropriate contracting officer."
On 01/16/12, Daniel Edlin wrote: > Major Cook,
> Please note that we are finalizing background materials on Theranos and will send them to you as soon as possible. I wanted to provide you with some other feedback per your questions during our conversation on Thursday. Theranos will in fact be able to provide GPS disabled devices, and we will be able to make modifications for you as well. With regard to the rough order of magnitude that would support a 12-month evaluation period, we kindly ask that you send a total list of assays you would like to test. With this information we will be able to confirm the feasibility of the timeline and magnitude of tests discussed last week.
> Thank you, and please indicate if you have any questions or would like to schedule a phone call to discuss further.
> Best regards, > Dan
>
>Original Message > From: Cook, Stephen D MAJ MIL USA USASOC > [mailto:stephen.d.cook@us.army.mil](javascript:main.compose() > Sent: Thursday, January 12, 2012 9:12 AM > To: Daniel Edlin > Subject: RE: Lab Set (UNCLASSIFIED)
> VNCLASSIFIED
> Dan, >
> Please send your phone number.>
> Steve >
> On 01/12/12, Daniel Edlin wrote: > > Major Cook,

```
> >
>> Please note we have learned that our emails have not been going through your mail delivery system, and we will try
again with our IT department tomorrow. In the meantime, please indicate your availability for a phone call to review in
detail the questions and concerns in your email below.
> > Thank you, I look forward to our next conversation.
> >
> > Best regards,
> > Dan
> >
>> ----Original Message-----
> > From: Daniel Edlin
> > Sent: Friday, January 06, 2012 5:36 PM
>> To: 'Cook, Stephen D MAJ MIL USA USASOC'
>> Cc: Elizabeth Holmes; 'michael.mcginnis@us.army.mil'
> > Subject: RE: Lab Set (UNCLASSIFIED)
> >
>> Thank you for your email, Steve. Hope you had a nice holiday. We are currently in the process of putting together
feedback and will have it to you shortly.
> >
> > Best regards,
> > Dan
> >
> >
>> -----Original Message-----
>> From: Cook, Stephen D MAJ MIL USA USASOC
>> [mailto:stephen.d.cook@us.army.mil](javascript:main.compose()(javasc
> > ript:main.compose()
> > Sent: Friday, January 06, 2012 6:57 AM
> > To: Elizabeth Holmes
> > Cc: michael.mcginnis@us.army.mil; Daniel Edlin
> > Subject: RE: Lab Set (UNCLASSIFIED)
> >
> > UNCLASSIFIED
> > Elizabeth, Dan,
>> Still waiting for feedback on the below inquiry. Based on your discussions with Kyle, trying to determine if our
assessment will be in the form of approximately 3ea devices over a trial 12-month service contract or if you'll have to
make mods or we'll have to make purchases to support an evaluation. I know Kyle had concerns with internal GPS
tracking and our requirement is to have this disabled in any devices we evaluate.
>> If you have any initial assessments in terms of rough order of magnitude that would support a 12-month evaluation
period, please provide that as well.
> >
>> Thank you for any feedback.
> >
> > Regards,
> >
>> Steve
> >
> >
> > On 12/15/11, Elizabeth Holmes wrote:
>>> Thanks Steve. Dan Edlin, copied to this email, is the Theranos Product Manager who will be overseeing this work
together. We will follow with feedback in line with your email below.
>>> We very much look forward to our coming conversations.
>>> Elizabeth.
>>>
>>> -----Original Message-----
>>> From: Cook, Stephen D MAJ MIL USA USASOC
```

>> script:main.compose()(javasc

>>> [mailto:stephen.d.cook@us.army.mil]

```
>> ript:main.compose()
> > Sent: Thursday, December 15, 2011 5:31 AM
>>> To: Elizabeth Holmes
>> Cc: michael.mcginnis@us.army.mil
>> Subject: Lab Set
>>>
>>> Ms. Holmes,
>>>
>>>
>>> My name is Steve Cook, my partner is Mike McGinnis - cc'd above, and the two of us will be working with Kyle Sims
through his requirement with you and Theranos. We were wondering if you could forward a summary of the existing
technology, your impression of where Kyle Sims would like to take the technology, any challenges from your perspective.
as well as your feedback on Kyle's initial comments below as they pertain to your current capabilities and further
work/investment required:
>>>
>> - More extensive environmental testing - Device function on board
>> evacuation platforms -Communications integration (what is the best method possibly as simple as an iridium phone
based on the bandwidth) -IT security considerations -Confidentiality. This system is considered disruptive technology and
as such Theranos has serious concerns about the details of their system getting out before they are prepared.
>>>
>>>
>> Your assessment and summary of the scope of the project as you understand it would be greatly appreciated.
>>>
>>>
>>> We look forward to working with you in the future.
>>>
>>>
>>> Regards.
>>>
>>>
> > Steve
>>>
>> Stephen Cook
>>> MAJ, SF
>> > APM Soldier Systems
>>>
                    (comm.)
>> "I am not a Contracting Officer, I cannot direct work or initiate or modify contracts; I do not have the authority to
commit the Government financially in any way. If the Government desires to alter your requirements as a result of the
information obtained from this email discussion, changes will be issued in writing and signed by the appropriate
contracting officer."
>>>
>>
> >
> > UNCLASSIFIED
> UNCLASSIFIED
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UNCLASSIFIED



USASOC & Theranos, Inc.

BACKGROUND

Theranos has created a point-of-service laboratory infrastructure that generates real-time data from a finger-stick of blood or other micro-volumes of different sample types delivering higher quality data than previously possible. This technology is an industry first, with profound effects on the ability to triage and stabilize patients via quantitative reads from micro sample sizes in real-time in the field.

- Each Theranos device can run every test currently available through the traditional centralized or hospital laboratory infrastructure.
- Theranos' device can process multiple samples on a given cartridge.
- include blood, urine, feces, tissue and saliva, amongst others.

 The device can process individual cartridges, or up to six (6) cartridges simultaneously, with a turnaround time of 5 30 minutes on any combination of tests ordered.
- The cartridge can automatically perform follow-up tests when protocol dictates those additional tests are necessary.
- Theranos manufactures all of its technologies and systems within the United States.
- Theranos has created the first CLIA-certified point-of-service laboratory technology, which is highly efficient in the provision of rapid information with a high level of accuracy for use in critical-need situations.

DIFFERENTIATION OF TECHNOLOGY

- In today's market, the variability inherent across different "point-of-care" devices is so great that accurate decision making has not been possible; likewise all such pointof-care devices are waived tests which are not accurate enough to be used for clinical decision making under regulatory guidelines.
- Theranos novel laboratory infrastructure generates data at unprecedented levels of quality and integrity by precisely automating the exact same laboratory processes run (manually) through central laboratories today.
- Devices can transmit data and video via satellite, short and long-wave radio, Ethernet, Wi-Fi, and cellular broadband to allow instant communication of test results to the necessary recipients.

IMPROVED PATIENT OUTCOMES AND MATERIAL COST REDUCTIONS

- Real-time data and decision support at the time of impact or injury
 - The Decision Support application gives real-time results and medical advice and instruction on patient laboratory values and how to stabilize, triage, and treat patients.
 - Upon communication of results, Theranos provides decision support for targeted interventions needed under specific conditions. This system enables doctors to make more informed decisions in complex scenarios and can facilitate the administration of basic care by untrained providers.



Enabling significant cost savings

- Theranos estimates fully loaded cost savings of 80% or more to USASOC by eliminating costs attributed to delayed triage and stabilization, prolonged hospital bed time, purchase of equipment and reagents, transportation of patients for testing in the field, laboratory personnel, and additional overhead expenses.

PROJECT SCOPE

- Military applications
 - Medevac: the ability to test and triage wounded soldiers at the time of impact and during evacuation (e.g. in a helicopter), and avoid delayed care due to unavailable medical information while the solider is in transit.
 - Genetic testing: real-time identification from small samples via DNA analysis at the point of service.
 - <u>Telecommunications</u>: device is equipped with software and hardware that enables live communication with offsite medical personnel, allowing the most qualified doctors and surgeons to assist in the stabilization, triage and initiation of treatment at the point-of-service. Theranos field systems' rugged, modular design with integrated communications capability and GPS enable full operability in the field.
 - Role 1-4: brings quick and accurate diagnostic capabilities to the field, performing basic health screenings for minor and severe illnesses (e.g. influenza), and sophisticated testing in real-time for infections, injuries, and more rapid transfusions. In addition, Theranos can collect longitudinal data to assist in infectious disease containment and identification of toxins and other infectious agents on the front-line as well as in more chronic disease management.
- Environmental Testing
 - Theranos hopes to work with USASOC to further develop environmental testing capabilities and looks forward to receiving guidance on any specifications needed to do so.
- IT Security
 - Theranos believes that interoperability with the USASOC system will not be difficult from either a connectivity or data interface standpoint based on feedback from previous interactions with DoD. Theranos will certainly integrate at the discretion of USASOC.
- Confidentiality
 - Given the disruptive and proprietary aspects of Theranos' technology, confidentiality is of the utmost importance. All details and procedures incorporated in this project must be strictly limited to USASOC and Theranos personnel on a need to know basis.



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EXHIBIT 2

Case 5:18-cr-00258-EJD Document 1396-3 Filed 04/08/22 Page 12 of 91

To: 'Chung, Kevin K LTC USA JC2RT'[kevin.k.chung@afghan.swa.army.mil]

Cc: Elizabeth Holmes[eholmes@theranos.com]

From: Daniel Edlin

Sent: Thur 3/8/2012 9:18:01 PM

Importance: High

Subject: RE: JCIDS (UNCLASSIFIED)

Received: Thur 3/8/2012 9:18:03 PM

DoD Briefing 03 08 2012 - CONFIDENTIAL.pdf

Dr. Chung,

Please use the attached PDF briefing for your presentation, and kindly delete the PowerPoint slides we sent you for confidentiality purposes. I meant to send you this briefing as a PDF.

If you ever need a raw document from us please let us know and we can go through the approval process to get it for you. My apologies for the confusion, and please let us know if you have any questions.

Best regards,

Dan

----Original Message-----

From: Daniel Edlin

Sent: Thursday, March 08, 2012 12:00 PM To: 'Chung, Kevin K LTC USA JC2RT'

Cc: Elizabeth Holmes

Subject: RE: JCIDS (UNCLASSIFIED)

Dr. Chung,

Please find the attached slides along with an overview document on Theranos for your reference. Please let us know if we can provide anything else; we will be available late tonight to support your presentation tomorrow. Note that we have never before sent these slides to anyone given the content is highly confidential as we prepare to broadly launch in the US commercial market this year. We appreciate all your support as always in maintaining the privacy of these documents on a need to know basis.

We look forward to our next conversation.

Best regards.

Dan

----Original Message-----

From: Chung, Kevin K LTC USA JC2RT [mailto:kevin.k.chung@afghan.swa.army.mil]

Sent: Wednesday, March 07, 2012 10:51 PM

To: Elizabeth Holmes Cc: Daniel Edlin

Subject: RE: JCIDS (UNCLASSIFIED)

Excellent. Thanks.

----Original Message----

From: Elizabeth Holmes [mailto:eholmes@theranos.com]

Sent: Thursday, March 08, 2012 11:20 AM To: Chung, Kevin K LTC USA JC2RT

Cc: Daniel Edlin

Subject: RE: JCIDS (UNCLASSIFIED)

I reviewed this today - you will have it tonight or at the latest early tomorrow AM PST.

From: Chung, Kevin K LTC USA JC2RT [kevin.k.chung@afghan.swa.army.mil]

Sent: Wednesday, March 07, 2012 8:13 PM

To: Elizabeth Holmes

Subject: RE: JCIDS (UNCLASSIFIED)

Classification: UNCLASSIFIED

Caveats: FOUO

My briefing is tomorrow morning...in 26 hours.

Please send me what you have.

Kevin

----Original Message----

From: Elizabeth Holmes [mailto:eholmes@theranos.com]

Sent: Wednesday, March 07, 2012 8:37 AM

To: Chung, Kevin K LTC USA JC2RT

Subject: RE: JCIDS

We'll include that,

----Original Message-----

From: Chung, Kevin K LTC USA JC2RT [mailto:kevin.k.chung@afghan.swa.army.mil] Sent: Tuesday, March 06, 2012 8:04 PM

To: Elizabeth Holmes Subject: RE: JCIDS

Oh and if you have a slide on IT requirements that would be very helpful.

Κ

----Original Message----

From: Elizabeth Holmes [mailto:eholmes@theranos.com]

Sent: Wednesday, March 07, 2012 8:22 AM

To: Chung, Kevin K LTC USA JC2RT

Subject: RE: JCIDS

Yes ... when is it and what is your area of focus

----Original Message-----

From: Chung, Kevin K LTC USA JC2RT [mailto:kevin.k.chung@afghan.swa.army.mil] Sent: Tuesday, March 06, 2012 7:50 PM

To: Elizabeth Holmes Subject: RE: JCIDS

Do you happen to have a short slide set I can use for my presentation to TF MED?

Thanks,

Kevin

----Original Message-----

From: Elizabeth Holmes [mailto:eholmes@theranos.com]

Sent: Tuesday, March 06, 2012 9:35 AM To: Chung, Kevin K LTC USA JC2RT

Subject: RE: JCIDS

Yes - that is fine. This is our complete CLIA lab test library.

Let me know if there is any other information from us that is of value for your meetings,

Talk to you soon,

Elizabeth.

----Original Message-----

From: Chung, Kevin K LTC USA JC2RT [mailto:kevin.k.chung@afghan.swa.army.mil] Sent: Monday, March 05, 2012 10:13 AM

To: Elizabeth Holmes Subject: RE: JCIDS

Thanks. Can I share this with our CLINOPS guy? He is the last person I need to convince in theater.

Kevin

----Original Message----

From: Elizabeth Holmes [mailto:eholmes@theranos.com]

Sent: Monday, March 05, 2012 10:15 AM To: Chung, Kevin K LTC USA JC2RT

Subject: RE: JCIDS

Kevin.

Please see attached.

Let me know if there are any other questions we can help answer,

Elizabeth.

----Original Message-----

From: Chung, Kevin K LTC USA JC2RT [mailto:kevin.k.chung@afghan.swa.army.mil] Sent: Tuesday, February 28, 2012 10:07 PM

To: Elizabeth Holmes Subject: RE: JCIDS

Elizabeth,

Do you have an updated users guide with list of available analytes you can send me?

Briefing some folks next week.

Thanks,

Kevin

From: Elizabeth Holmes [mailto:eholmes@theranos.com]

Sent: Sat 2/25/2012 1:12 AM

To: Edgar, Erin P COL MIL USA USCENTCOM CCSG-A; Chung, Kevin K LTC USA JC2RT

Cc: Huntsinger, Charles R Mr CIV USAF USCENTCOM CCSG-AXO; Murphy, Christine L Maj MIL USAF USCENTCOM

CCSG-AA; Haddad, Sam E JR LTC MIL USA USCENTCOM CCJ4-O-LRC

Subject: RE: JCIDS

Thanks Colonel Edgar.

We will review this in parallel with our people today,

Elizabeth.

From: Edgar, Erin P COL MIL USA USCENTCOM CCSG-A [mailto:erin.edgar@centcom.mil]

Sent: Friday, February 24, 2012 12:23 PM

To: Elizabeth Holmes; Chung, Kevin K LTC USA JC2RT

Cc: Huntsinger, Charles R Mr CIV USAF USCENTCOM CCSG-AXO; Murphy, Christine L Maj MIL USAF USCENTCOM

CCSG-AA; Haddad, Sam E JR LTC MIL USA USCENTCOM CCJ4-O-LRC

Subject: JCIDS

Team,

Lots of acronyms thrown out in this morning's TELCON w/ the lab consultants, Tricare Management Activity, Medical Research and Materiel Command, and us. JCIDS is the Joint Capabilities Integration Development System. Attached is a new manual that describes it briefly.

We just finished a mtng w/ the J8 Science and Technology guys, and they think that a JEON would be the appropriate vehicle for this (Joint Emerging Operational Need). UON/JUON/JEON do NOT require ICDs and CCDs, but they'll eventually require some sweat and paperwork if they are to be sustained.

I see us in two parallel Lines of Effort: 1) Get a couple of analyzers to BAF ASAP for proof of concept testing and see how they plug into our IT system. We are trying to piggy-back onto the USASOC contract w/ MSG Sims so we don't have to start from scratch. 2) Develop a JEON and have Gen Mattis send notes of support to the CGs at AMEDD center and School and MRMC.

-E

Classification: UNCLASSIFIED

Caveats: FOUO

Confidential Briefing US Department of Defense

This presentation and its contents are Theranos proprietary and confidential.

Contents

Background on Theranos

Theranos Systems Overview

The Clinical Laboratory

Cost Savings

redefining healthcare

Clinical Deep-dive

Theranos, Inc.

Theranos is a Silicon Valley-based healthcare technology company founded in 2003.

- Theranos' proprietary, patented technology runs comprehensive blood tests from a finger-stick and tests from micro-samples of other matrices in realtime outside of traditional lab settings and generates significantly higher integrity data than currently possible.
- Our current and past clients include 10 of the top 15 major pharmaceutical companies, midsized bio-pharmas, prominent research institutions, healthcare payors, and U.S. and foreign government health and military organizations.
- Theranos is now launching Theranos Systems to providers nationally.

Theranos Confidential :

About Theranos

Founder and CEO **Elizabeth Holmes** left Stanford University to start Theranos around her patents for next-generation healthcare systems, building the company from inception to rapid commercial growth today.

President & COO **Sunny Balwani** joined Theranos from the graduate studies program in Computer Science at Stanford University after successfully selling his previous company for over \$400M.

Theranos' investors and board members include, amongst others:

- Larry Ellison, Founder and CEO of Oracle Corporation
- George P. Shultz, former U.S. Secretary of State, U.S. Secretary of Labor, U.S. Secretary of the Treasury, Director of OMB, Dean of the University of Chicago Graduate School of Business, and President of Bechtel
- **Bob Shapiro**, former CEO and Chairman of Monsanto and Pharmacia Corporations (now Pfizer); former director of NYSE, Citibank, and other major corporations
- Donald L. Lucas, the first venture capitalist in Silicon Valley, and a legend behind many of today's Fortune 500 companies

Theranos Confidential

Theranos is certified as a High Complexity CLIA Laboratory

Clinical Laboratory Improvement Amendment of 1988

- CLIA regulates all testing on humans for health purposes using quality standards
 - The more complex the test, the more stringent the standards
- Ensures accurate, reliable testing regardless of location
- Administered by

FOIA Confidential Treatment Requested by Theranos

redefining healthcare









Complexities (as defined by CMS)

- Waived simple, accurate tests without routine oversight
- Moderate most tests fall in this category; automated testing where the lab must meet standards and surveyed biennially
- PPM provider performed microscopy; the lab must meet quality standards; no routine oversight
- High Complexity requires the highest level of training, technique and result interpretation; most stringent standards; labs are surveyed routinely and randomly



theranos

- Certification as a high complexity lab under CLIA
- Theranos clinical analyzers are Class I analyzers under FDA 21 CFR Parts 862-892

Theranos Confidential

TS-0325091



Theranos' Quality Standards Under CLIA

- Personnel qualifications & responsibilities lab director has overall responsibility; supervision of required positions
- Quality Control (QC) mechanism to ensure all testing procedures meet highest standards
- Specimen Integrity and Record Keeping documentation of all test data; patient identification, confidentiality, test referrals, etc.
- Proficiency Testing (PT) testing for accuracy and control comparisons; biennial audits of testing accuracy
- Quality Assessment (QA) ongoing assessments;
 comprehensive system to monitor performance and ensure quality results

CLIA Surveys and Audits

Biennial

redefining healthcare

- Performed by CMS trained State Agency Medical Technicians or approved accrediting organizations with equivalent standards (CAP)
- Outcome-oriented with QA focus
- Data indicates improved lab performance over time

Theranos maintains CLIA accreditation as a high complexity lab and has passed audits without a single deficiency to maintain this status



Theranos Hardware

Theranos field systems' rugged, modular design with integrated communications capability and GPS enable full operability in the field

Modular Design

- Can be used in all military care facilities First Aid and Triage Shelter (Level I), Portable Surgical Centers (Level II), Field Hospitals (Level III)
- Blade design allows for customization (e.g., battery)
- Peripheral capabilities for additional biometric data collection

Integrated Communications

- Integrated communications with GPS give full operability in the field
- Can communicate via satellite, short and long-band radio, wireless communications, cellular communications, Ethernet connection
- High resolution camera allows for two-way video conferencing or teleconferencing with doctors not in the field

Range of Operability

System has been validated to perform under a wide range of temperatures, humidity, and atmospheric pressure (elevation)

Contents

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redefining healthcare

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redefining healthcare







Cartridges

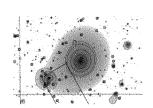


Mobile Applications – e.g., the *Health Assistant*

Theranos Systems: Backend Analytical Infrastructure



Data Analysis Infrastructure



Pattern Recognition Algorithms



Applications e.g., Integration, Individualized CDS, Videoconferencing.

Theranos Systems

- Unlike existing point of care technologies, Theranos analyzers run any test available in central laboratories
- Theranos is capable of running any combination of test within the same cartridge footprint
- Cartridges are laid out based on frequency of tests ordered and ability to run automatic "reflex" tests for follow-on test orders for out-of-range values which otherwise would require a separate sample
- Automated processing eliminates error due to "passive" point of care processing or human processing in labs
- Link to analytical system on Theranos servers facilitates intelligent sample processing and actionable decision making

Theranos Confidential 12



Theranos Systems Capabilities

Theranos is a fully integrated health data capture, analysis and care delivery solution enabling better diagnoses, early detection of health status, rapid intervention and improved quality of care

- ✓ Quick test turnaround and real-time access to results
- ✓ Point-of-service automated sample analysis
 - Eliminates human lab errors and sample degradation issues
- Diversified number of tests greatly expands upon current combat medical capabilities
- ✓ Automated reflex testing without the need for additional labs
- ✓ Decision support, visualization and analysis tools around individual biochemical profiles and traditional CDS guidelines
- √ High integrity longitudinal data
 - Allows for trend characterization over time; rates of change of biochemical data are better indicators of disease progression than static concentrations
- √ No/minimal setup and training time required



Theranos Connectivity Modes

- The Theranos System is equipped with software and hardware that enables live communication with offsite medical personnel, allowing the most qualified doctors and surgeons to assist in the stabilization, triage and initiation of treatment at the point-of-service.
- Theranos field systems' rugged, modular design with integrated communications capability and optional GPS enable full operability in the field.
- Analyzers can transmit data and video via the following methods to allow instant communication of test results to the necessary recipients:











Satellite

Ethernet

Short/long wave radio

Cellular **Broadband**

Wi-Fi

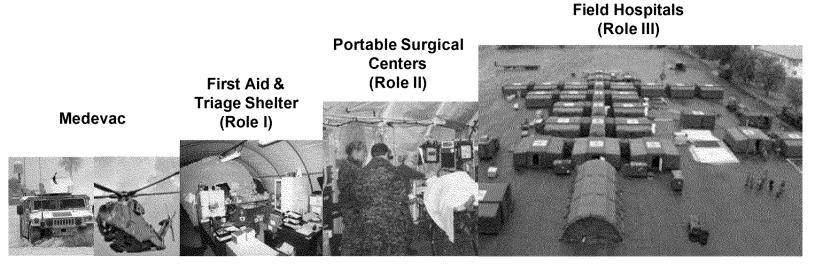
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TS-0325099

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Modular Design of Theranos System

Theranos systems modular design allows for portability and deployment in all military medical care settings



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Theranos IT Infrastructure

- Highly versatile in connectivity platform we have integrated GSM and CDMA cellular data cards into every analyzer with Wi-Fi connectivity. In the past our analyzer has communicated over port 8443, 22, or 443, and TCP/IP HTTPS. However, we have the ability to configure ports based on customers' IT needs.
- Configuration The analyzer communications are commonly configured via DHCP, which automatically selects IP address, subnet and gateway. Additionally, the analyzer can be customized to accept input of static IP, subnet and gateway.
- Operating System We use a custom image of Windows 7P Embedded as our main OS, however, we have also used Linux in the past without any problems. We usually find Windows 7E to be more powerful and it allows us to provide more capabilities.
- Security Policies –Theranos is HIPAA and 21 CFT Part 11 compliant, utilizes bank-level encryption, and operates in compliance with FIPS 140.

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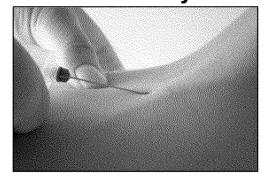
redefining healthcare



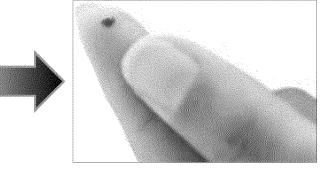


Close-Out

Lab Today



Theranos

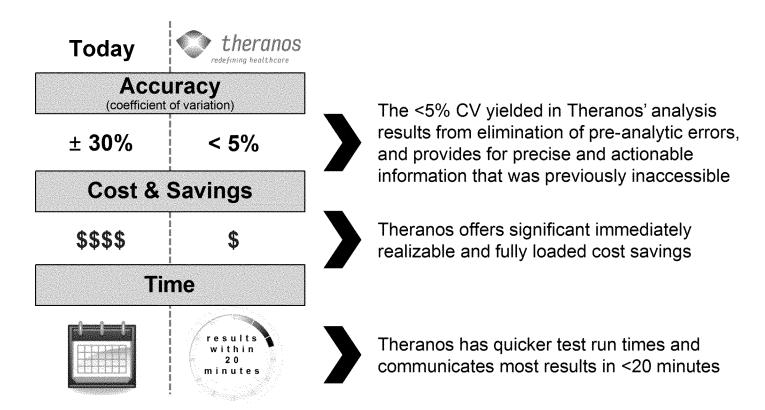


Finger-stick tests reduce volumes of blood draws by 99%

Major impact on **patient experience**: pediatrics, geriatrics, oncology, etc.



Theranos Reinvents the Clinical Laboratory





Finger-Stick Based Testing

Routine, Specialty & Esoteric Tests

- All 2000+ currently run tests/CPT codes are available through Theranos
- Theranos runs any test available in central laboratories
- Theranos can process any sample type
- All tests match existing reimbursement codes
- With CLIA certification, Theranos is a nationally accredited provider

Higher Quality Data

- Variability among traditional labs prevents insight into:
 - Early disease onset, progression, and regression
- The unprecedented lack of variation with Theranos yields:
 - Higher integrity data and longitudinal trending
 - Earlier insight into the onset/progression of disease
 - Reduction in unnecessary secondary procedures from results which currently show up as false positive results

Validation of Theranos Systems

Theranos Systems have been comprehensively validated over the course of the last seven years by ten of the fifteen largest pharmaceutical companies, with hundreds of thousands of assays processed.

After running clinical trials with Theranos Systems instead of the central laboratory, a top-five pharmaceutical company's Lab Director concluded that "Theranos Systems eliminate the need for a lab."

Theranos Systems are validated under FDA YCH and guidelines.







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Excerpts from Theranos' 2,000+ Test Menu

<u>Bacteria</u>	BCBSWY - Cor	nplete Blood Count w	<u>Complete</u>	Cardiovascular Panel
Streptococcus pneumoniae (penic R(24%),S)		<u>Diff</u>	Metabolic Panel	Creatinine
Mycoplasma pneumoniae	White blood cell count		HGB A1c	Kinase
Chlamydia pneumoniae	Red blood cell cou	Red blood cell count		Troponin-I
Bordetella pertussis	Hemoglobin		Calcium	Troponin-t
Haemophilus influenzae (ampic R,S)	Hematocrit		Albumin	CRP- High-Sensitivity & LS
Moraxella catarrhalis	Mean corpuscular volume		Total Protein	Homocysteine
Staphylococcus aureus (MR (30%), RS)	Mean corpuscular	Mean corpuscular hemoglobin		Lipid Profile & Glucose
Streptococcus pyogenes (A)	Mean corpuscular	hemoglobin concentration		Panel
Streptococcus agalactiae (B)	Platelet count		CO2	Cholesterol
Pseudomonas spp (aeruginosa)	Mean platelet volu	me	Chloride	HDL
Haemophilus parainfluenzae	Renal Panel	Liver Panel	BUN	LDL
Enterobacteriaceae spp	Albumin		Creatinine	LDL/HDL Ratio
Legionella spp	BUN	ALT	ALP	Triglycerides
gram-negative bacteria	Calcium	Alkaline Phosphatase	ALT	VLDL
Escherichia coli	CO2	AST	AST	STDs & Drugs of Abuse
<u>Viral</u>	Chloride	Ferritin	Bilirubin	and the second s
H5N1, H1N1	Glucose	GGT	Magnesium I	Chylmd Trach, Dna, Amp Probe
H3N2, Infl. B	Phosphorous	Iron	Ipecac	N.Gonorrhoeae, Dna, Amp Prob
Rhino Virus	Potassium		Lsd,	Hpv, Dna, Amp Probe
Adenovirus	Sodium	Lactate Dehydrogenase	Lsd-25,	Acid
RSV	Creatinine	Microalbumin	Lysergide,	Butorphanol
parainfluenza virus (1,2,3,4)	eGFR	Total Protein	Nalbuphine	D-Lysergicacid Diethylamide,
Coronaviruses	Thursid Dansl	Albumin	Nubain{R}	Dolophine,
human metapneumovirus (HMPV)	Thyroid Panel TSH	Globulin	Rohipnolâ®	Flunitrazepam
*105 Tests Shown, Another 20+	T-3	Bilirubin Direct	Stadolâ®	Hairstat
pages show all available tests w/	T-4	Bilirubin Total	Ethyl Glucuronide,	Heroin,

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Cost Savings Through Theranos' Pricing Model

- Theranos is pricing each of our tests at 30% of the Medicare fee schedule for US commercial use.
- The only costs associated with Theranos' US commercial deployments to providers are on a per-test basis.
 - As such, Theranos eliminates the costs of phlebotomists, multiple analyzers, reagents that may or may not be used, multiple humans processing each test, processing equipment, the costs associated with discarding tests that are no longer usable due to potential temperature fluctuations in certain environments, as well as the cost of having to fly patients out of the country or to off-site locations where laboratory testing infrastructures are in place.
- Theranos has built electronic billing systems which can help facilitate payment logistics processes.



Cost Savings Through Infrastructure Investments

Theranos is making large investments in infrastructure to facilitate rollout, and has historically assumed the costs associated with the following:

- Cost of manufacturing, shipping, handling, maintenance. All repairs and services.
- Training and certification at all sites
- 24x7 call center support
- On-site laboratory tech support
- All shipping, handling and inventory management costs
- Patient kits
- Data communication costs
- Data Security, data encryption and related costs for data integration
- Routers for data communication as needed
- Biometric capture capabilities as needed for screening
- Remote monitoring for quality
- Decision support systems
- Clinical decision support applications
- Software systems to interface with EMR systems
- Software Systems to interface with hospital systems
- **.** . . .

Selected Assay Pricing List

The following examples represent a selection from the Theranos test menu.

<u>TEST</u>	Theranos US Commercial Pricing
CMP (Albumin, Billrubin, Calcium, Chloride, Creatinine, Carbon Dioxide, Glucose, Alkaline Phosphatase, Potassium, Protein, Sodium, Aspartate Aminotransferase, Urea Nitrogen, GFR, Albumin/Globulin, Anion Gap	
Albumin (serum)	\$2.12
Albumin (urine)	\$2.20
Bilirubin	\$2.13
Chloride	\$1.95
Creatinine	\$2.18
Carbon Dioxide	\$2.08
Glucose	\$1.67
alkaline Phosphatase	\$2.20
Potassium	\$1.95
Protein	\$1.56
Sodium	\$2.05
Aspartate Aminotransferase	\$2.20
Urea Nitrogen	\$1.68
GFR	\$1.90
Albumin/Globulin	\$2.10
Anion Gap	\$1.90

Note: Theranos is making the following prices available in the US commercial market. If significant customization or other requirements are needed for potential programs, costs may vary.

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<u>TEST</u>	Theranos US Commercial Pricing
Lipid (Cholesterol, Triglyceride, HDL Chol, LDL Chol, VLDL Chol, Cholesterol/HDL	
Cholesterol)	
Cholesterol	\$1.85
Triglyceride	\$2.45
HDL Chol	\$3.48
LDL Chol	\$3.48
VLDL Chol	\$4.94
Cholesterol/HDL Cholesterol	\$1.85
CBC (WBC, RBC, Hemoglobin, Hematocrit, MCV, MCH, MCHC, RDW CV, Platelets,	
MPV, Neutrophils, Monocytes, Eosinophils, Basophils)	
WBC	\$3.31
Neutrophils	
Monocytes	
Eosinophils	
Basophils	
RBC	\$1.28
Hemoglobin	\$1.01
Hematocrit	\$1.01
MCV	\$1.01
MCH	\$1.01
MCHC	\$1.01
RDW CV	\$1.01
Platelets	\$1.90
MPV	\$1.01

<u>TEST</u>	Theranos US Commercial Pricing
LFT (Albumin, Bilirubin Direct, Bilirubin, Alkaline Phosphatase, Alanine	and the second
Aminotransferase, Aspartate Aminotransferase, Protein)	
Albumin	\$2.12
Bilirubin Direct	\$2.13
Bilirubin	\$2.13
alkaline Phosphatase	\$2.20
Alanine Aminotransferase	\$2.25
Aspartate Aminotransferase	\$2.20
Protein	\$1.56
BMP (Urea Nitrogen, Carbon Dioxide, Chloride, Creatinine, Glucose, Potassium, Sodium, Calcium, Anion Gap, GFR)	
Urea Nitrogen	\$1.68
Carbon Dioxide	\$2.08
Chloride	\$1.95
Creatinine	\$2.18
Glucose	\$1.67
Potassium	\$1.95
Sodium	\$2.05
Calcium	\$2.19
Anion Gap	\$2.19
GFR	\$2.19

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<u>TEST</u>	<u>Theranos US</u> Commercial Pricing
Troponin (Troponin T Cardiac)	\$4.18
CK (CK)	\$2.77
PT/PTT/INR (Prtime, INR) - Prothrombin time	\$1.67
PT/PTT/INR (Prtime, INR) - Thromboplastin time, partial	\$2.55
Free T4 (Free T4)	\$2.75
HIV (HIV) - HIV-1	\$3.77
HIV (HIV) - HIV-2	\$5.74
HIV (HIV) - Hiv-1/hiv-2 single result	\$5.83
HIV (HIV) - Hiv-1 dna amp probe	\$14.91
HIV (HIV) - Hiv-2 dna amp probe	\$14.91
B Strep (B Strep)	\$14.91
Epstein Barr (Epstein Barr)	\$5.57
Epstein Barr (Epstein Barr)	\$7.71
Mono (Mono)	\$11.38
Blood Type (Blood Type) - ABO	\$1.27
Blood Type (Blood Type) - Rh	\$1.27
Lead (Lead)	\$5.15
Lead ZPP (Protophorphyrin Zinc)	\$6.10

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<u>TEST</u>	Theranos US Commercial Pricing
A1C (A1C)	\$4.13
Hep C Antibody (Hep C Antibody)	\$6.07
RPR (Reagin AB)	\$1.82
PSA (Prostate Specific Ag)	\$7.82
Amylase (Amylase)	\$2.75
Lipase (Lipase)	\$2.93
TSH (TSH)	\$7.14
GGT (Gamma Glutamyl Transferase)	\$3.06
Base Excess/Base Deficit (Base Excess/Base Deficit)	\$3.06
Additional tests of interest include pH, West Nile Virus, Chagas Disease, Malaria, and Dengue.	
рН	\$1.52
West Nile Virus	\$7.16
Chagas Disease	\$5.27
Malaria	\$5.60
Dengue	\$5.48

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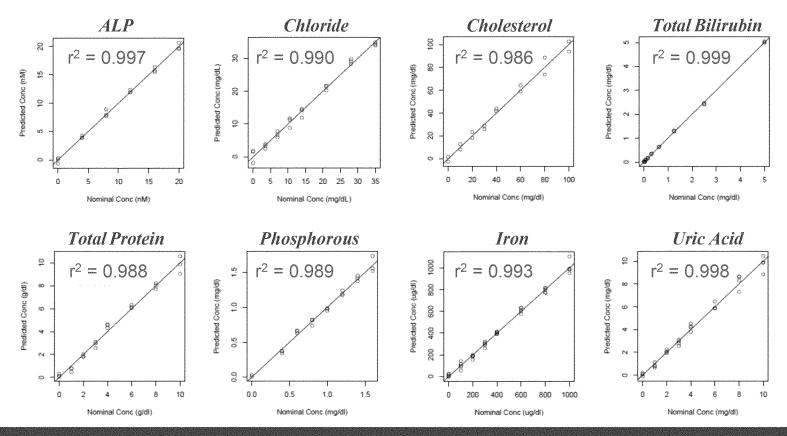
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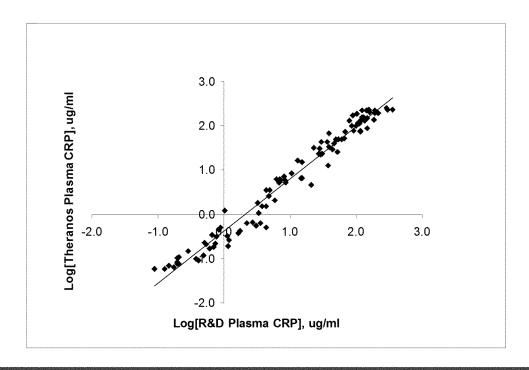
Routine Test Validations Demonstrate High Correlation Coefficients Across Clinical Range



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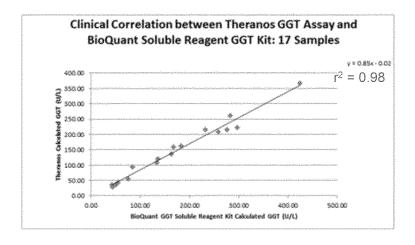
CRP Test Correlation to Reference Methods Over 10,000-fold Range

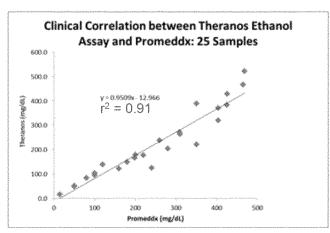
$$y = 1.179x - 0.3746$$
, $r2 = 0.99$, $N = 104$



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General Chemistries

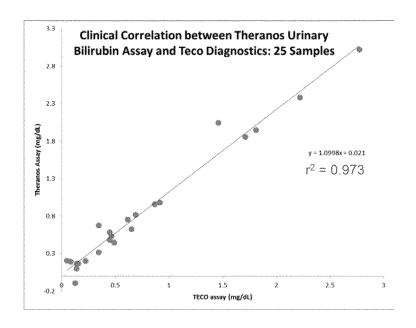




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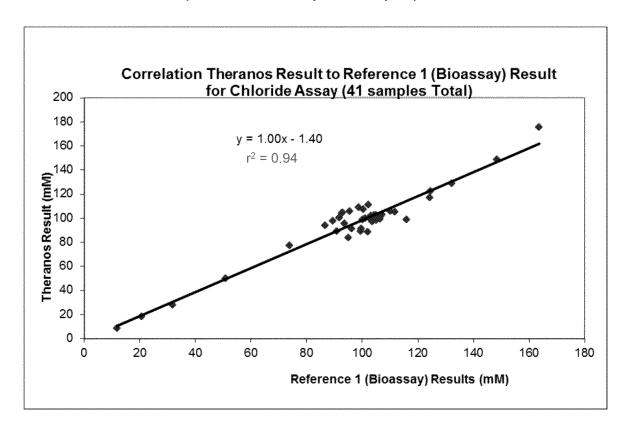


Assays in Sample Types Other Than Blood





(N = 41 clinical + spiked samples)

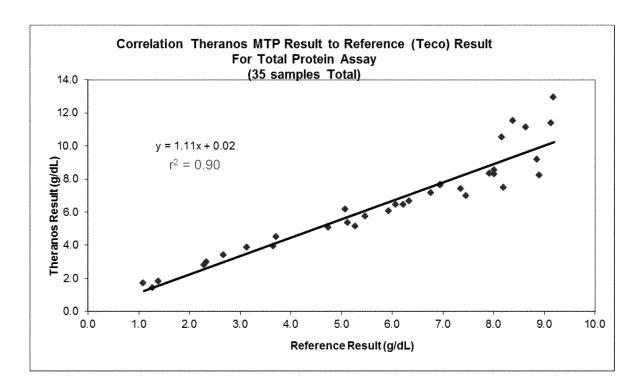


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Total Protein

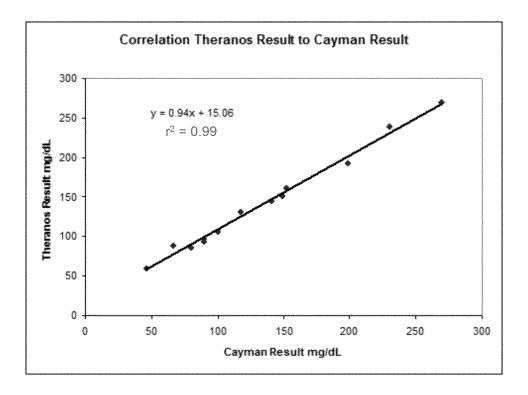
(N = 35 clinical samples)





Glucose

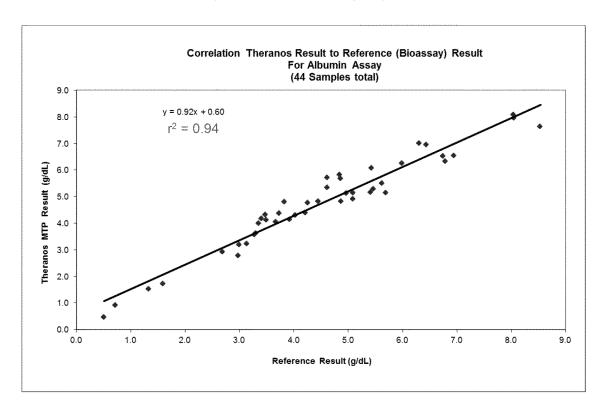
(N = 13 clinical samples)





Albumin

(N = 44 clinical samples)

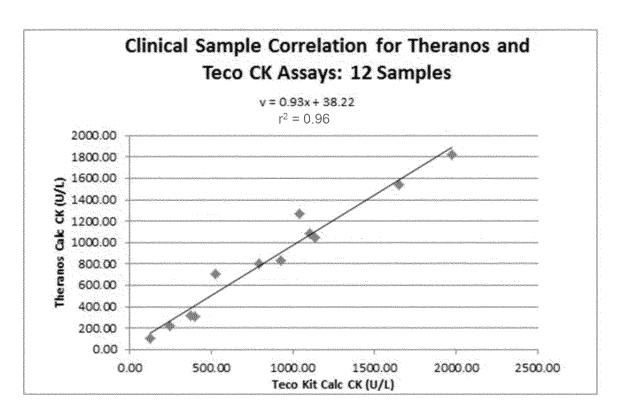


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Creatine Kinase

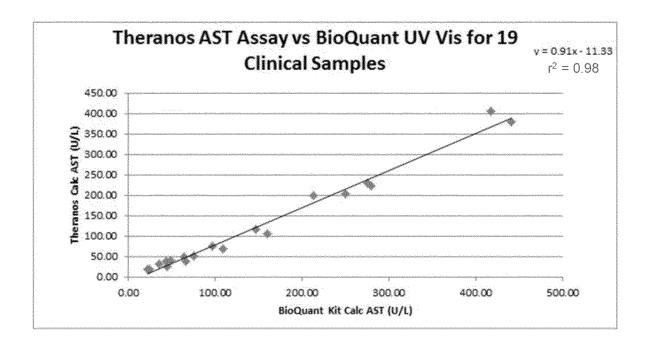
(N = 12 clinical samples)



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Aspartate Aminotransferase

(N = 19 clinical samples)

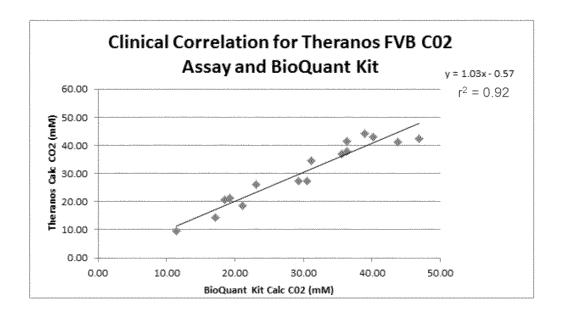


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Carbon Dioxide

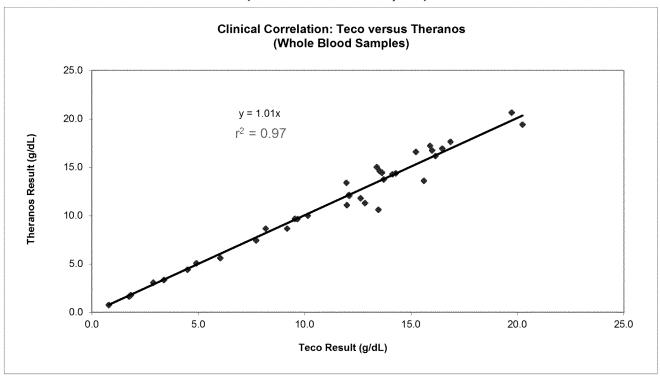
(N = 16 clinical samples)





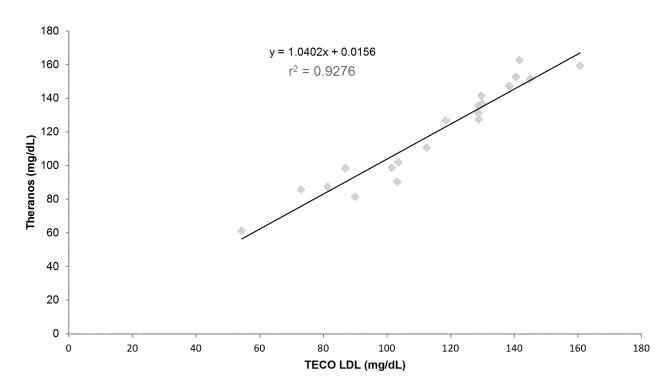
Hemoglobin

(N = 36 clinical samples)



Direct LDL-Cholesterol

(N = 20 clinical samples)

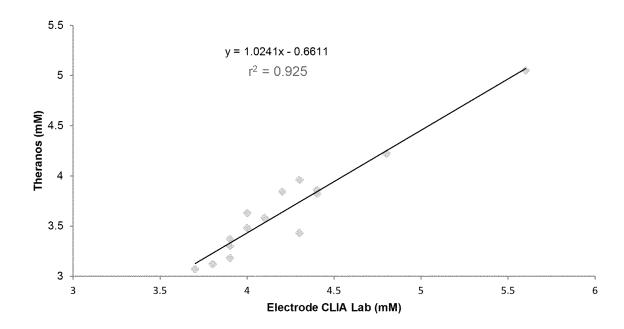


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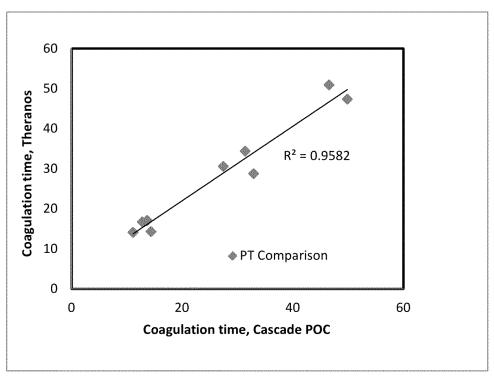
Potassium

(N = 15 clinical samples)



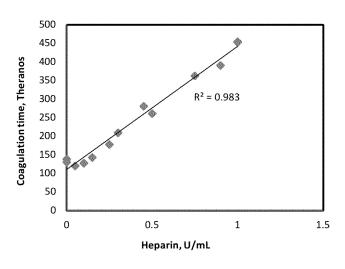


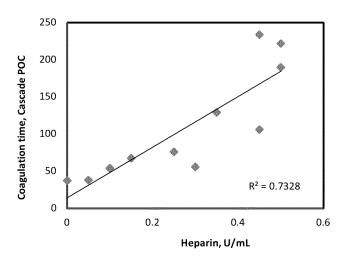
PT results – Clinical samples of patients on Coumadin



- Reference method: Cascade POC, Helena Laboratories, 35uL of undiluted Citrate plasma.
- Theranos method: 2uL of 5X diluted EDTA plasma.
- Excellent correlation between the two measurement sets.

aPTT results - Plasma spiked with Heparin

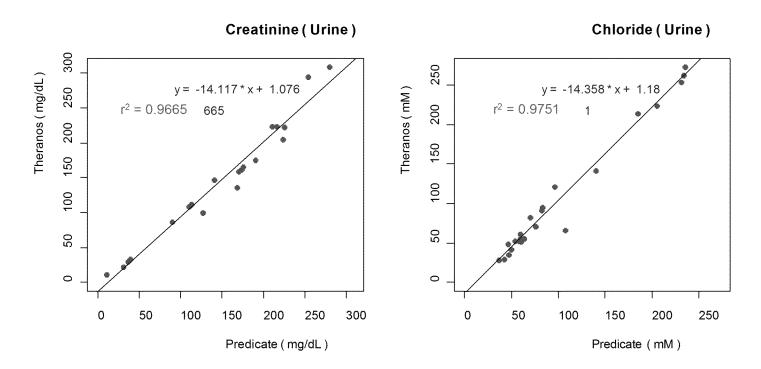




- Reference method: Cascade POC, Helena Laboratories, **35uL of undiluted plasma** spiked with Heparin.
- Theranos method: 2uL of 5X diluted plasma.
- Theranos method shows a better correlation with spiked Heparin compared to the Cascade system.

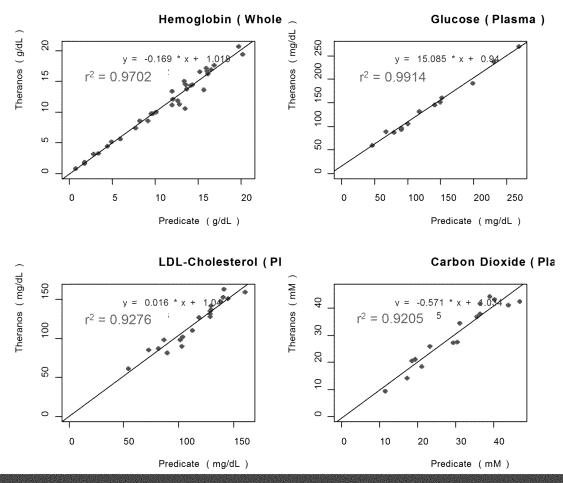
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Urine Based Assays



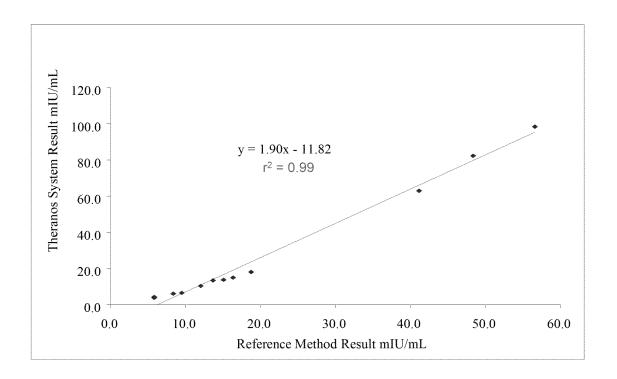
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General Chemistries



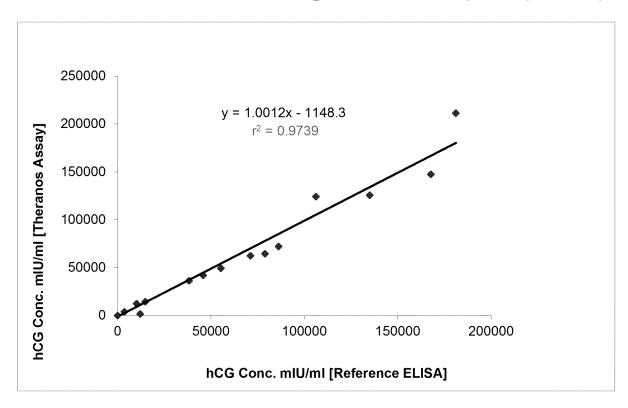
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Follicle stimulating Hormone (FSH)



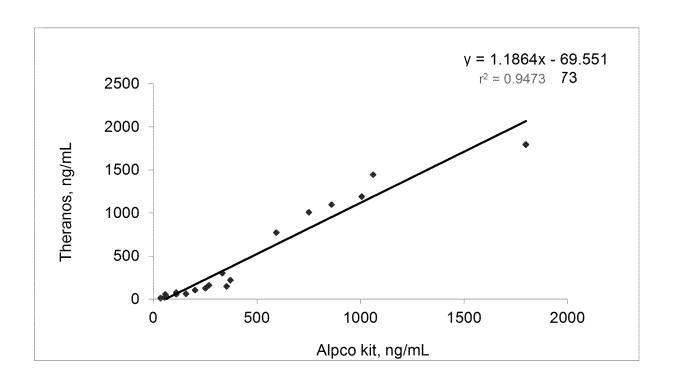
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Human chorionic gonadotropin (hCG)



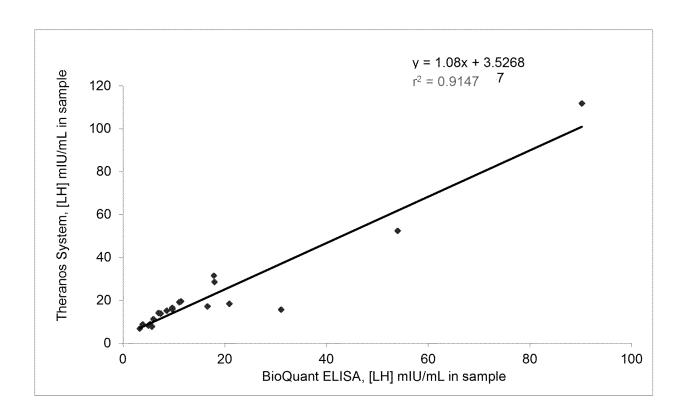
Theranos Confidential 51

IgE



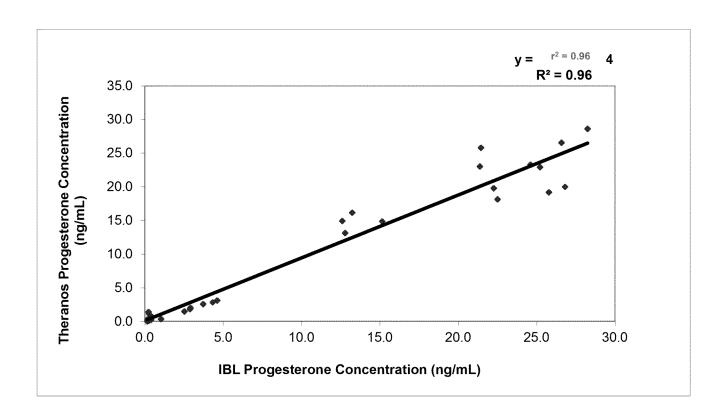
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Luteinizing Hormone (LH)



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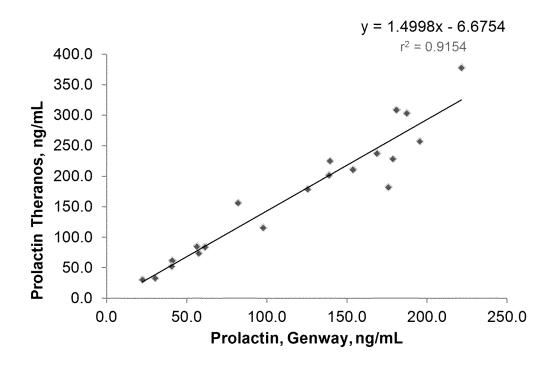
Progesterone



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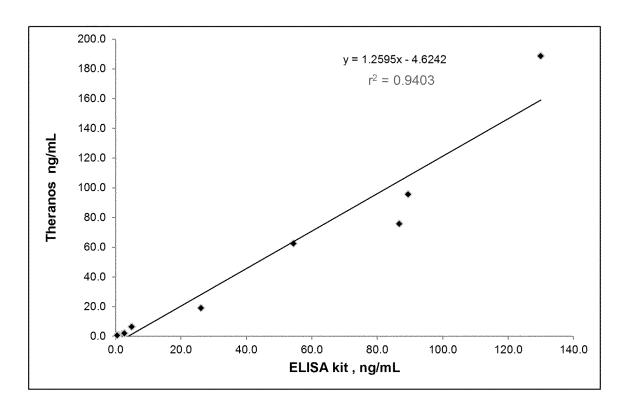


Prolactin

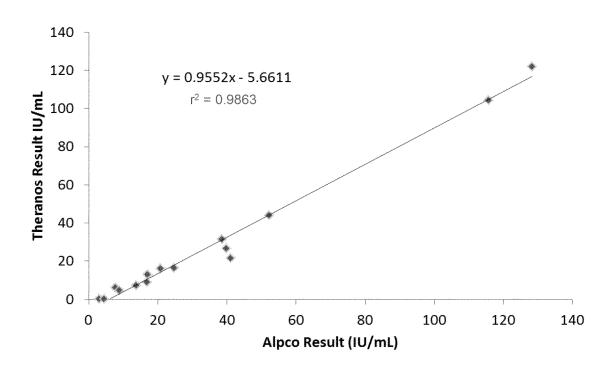




Total PSA

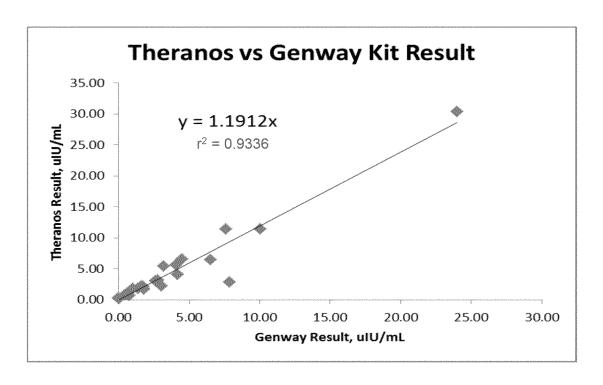


Rubella Antibody



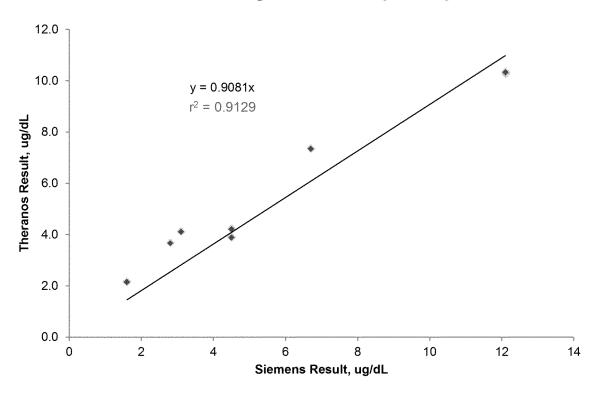
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Thyroid stimulating hormone



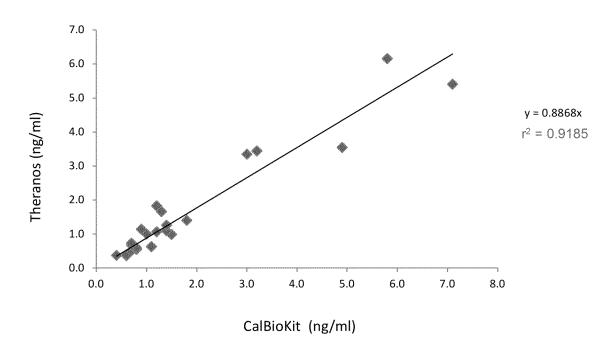
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Total Thyroxine (TT4)



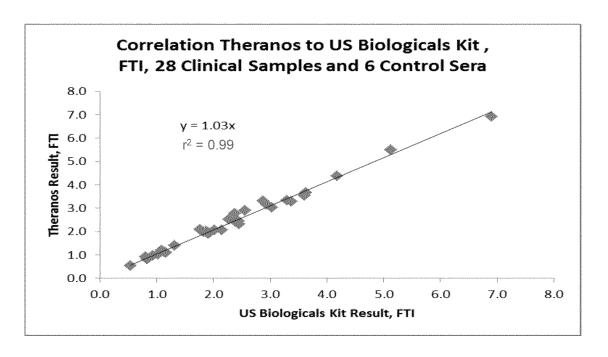
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Total T3



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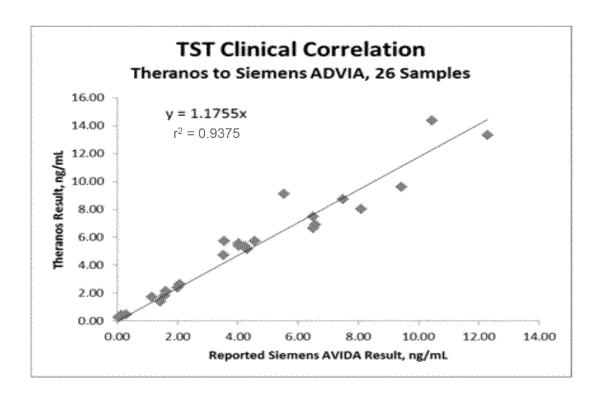
T3 Uptake assay



The T Uptake % is used to compute the Free Thyroxine Index (FTI) from the Total T4

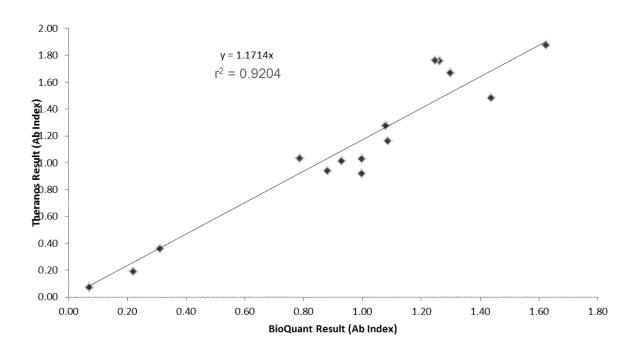
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Total Testosterone



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Varicella Zoster virus - IgG





Precision and Accuracy for 3 Days/Lots, Concentration (IU/mL) N = 3 cartridges per point

redefining healthcare

		Day/Lot 1			Day/Lot 2			Day/Lot 3			Inter-Lot	
[VZV IgG] IU/mL	Mean Conc.	CV %	% Rec.									
11.00	9.97	22.3	91	11.40	9.5	104	9.83	33.6	89	10.47	18.9	95
5.50	4.65	2.4	85	6.65	13.6	121	6.09	15.9	111	5.94	18.5	108
2.75	2.33	15.3	85	3.07	7.3	112	2.65	8.1	96	2.68	14.9	98
1.38	1.27	13.5	92	1.46	10.6	106	1.46	12.3	107	1.40	12.6	101
0.69	0.65	11.1	94	0.75	6.7	109	0.71	6.9	104	0.70	9.6	102
0.34	0.32	7.8	93	0.34	13.7	98	0,35	4.0	103	0.34	9.2	98
0.17	0.17	9.2	99	0.18	9.7	105	0.17	1.9	98	0.17	7.5	101
0	OORL	-	-									
Positive Control	4.25	8.6	-	3.70	11.7		4.25	9.3		4.05	11.0	-
Negative Control	OORL	-	-									



VZV – IgG Precision

Inter-Analyzer Precision, Concentration (IU/mL)

				Intra-Cartri	idge	Inter-C	artridge
Analyzer	Tip 1	Tip 2	Mean	CV %	% Recovery	Mean	CV %
1	0.26	0.27	0.26	4.1	86	0.31	7.2
2	0.34	0.35	0.35	1.1	113		
3	0.30	0.36	0.33	11.4	108		
4	0.26	0.28	0.27	4.8	89		
5	0.30	0.31	0.30	2.1	99		
6	0.28	0.27	0.28	3.6	90		
7	0.29	0.31	0.30	2.7	98		
8	0.32	0.32	0.32	0.3	104		
9	0.30	0.28	0.29	6.1	95		
10	0.32	0.33	0.32	1.0	106		
11	0.28	0.27	0.27	0.8	89		
12	0.30	0.32	0.31	4.4	100		
13	0.29	0.32	0.31	7.5	100		
14	0.35	0.32	0.34	4.8	109		
15	0.35	0.33	0.34	4.0	111		
16	0.31	0.31	0.31	1.2	101		
17	0.29	0.33	0.31	8.8	100		
18	0.31	0.25	0.28	16.8	91		
19	0.32	0.29	0.30	6.3	99		
20	0.29	0.31	0.30	5.9	98		
21	0.30	0.32	0.31	4.3	100		
22	0.33	0.31	0.32	4.7	104		
23	0.33	0.32	0.32	1.9	105		
24	0.33	0.31	0.32	5.0	103		

Estradiol – Precision

QC Levels for 3 Day Precision and Accuracy

Nominal	Cartrid			Recovere	d [Estradiol]	pg/mL	
[Estradiol] pg/mL	ge	Day 1	Day 2	Day 3	Mean Conc.	CV %	% Recovery
478.50	1	522	481	448	455	8	95
	2	402	426	485			
	3	440	444	444			
92.63	1	114	104	72	92	14	99
	2	104	91	85			
	3	90	81	87			
45.38	1	36	37	37	41	11	90
	2	40	38	44			
	3	44	48	44			

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Estradiol - Precision

	Signal	Cona	
Analyzer	Mean RLU	Difference from Mean	Conc. pg/mL
1	9287	-5	74
2	9523	-2	71
3	9991	2	66
4	10160	4	64
5	9397	-4	72
6	10383	7	62
7	10275	5	63
8	10351	6	62
9	8432	-14	84
10	8334	-15	86
11	9041	-7	77
12	9457	-3	72
13	10687	10	59
14	10984	13	57
15	10704	10	59
16	10823	11	58
17	10125	4	65
18	10222	5	64
19	10168	4	64
20	10452	7	61
21	8832	- 9	79
22	8365	-14	85
23	8425	-14	84
24	9562	-2	71

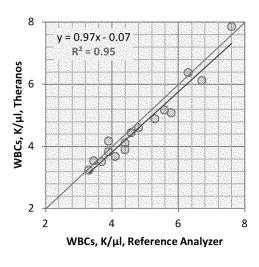
Inter-Analyzer Concentration CVs						
Mean Conc. pg/mL	StD ev	CV%	% Recovery			
69	9	13	92			

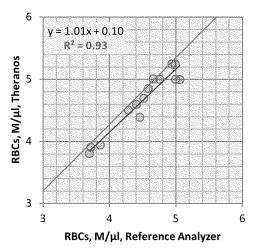
Inter-Analyzer Signal CVs						
Mean RLU	StDev	CV%				
9749	835	9				

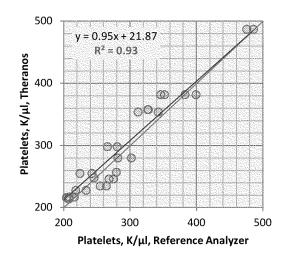
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Total WBC, RBC and Platelet Counts: correlation between reference analyzer and Theranos platform



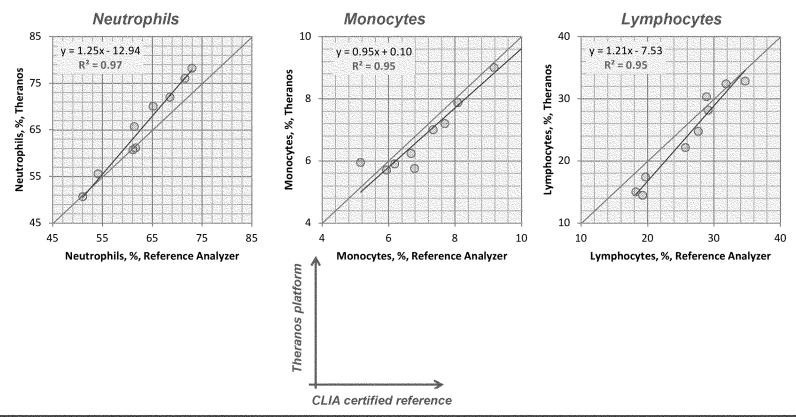




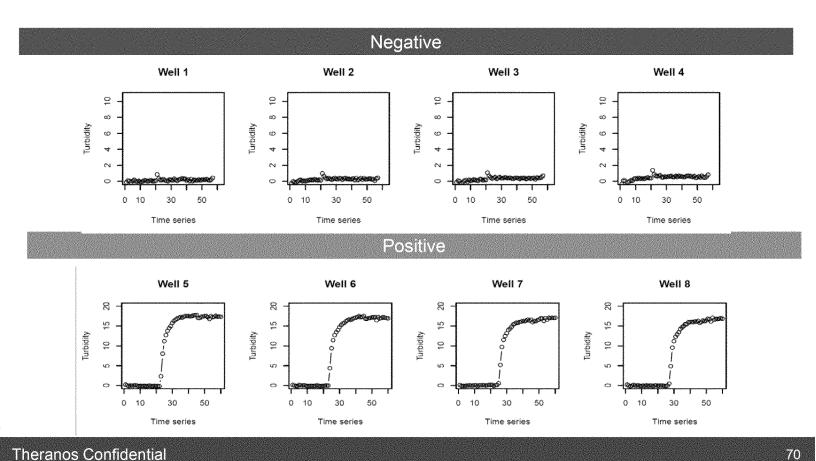


Correlation of WBC-differential assay between Theranos platform and reference hematology analyzer

All numbers are WBC cell type proportions expressed as percentages of total WBC



NAA detection (E. Coli O157)



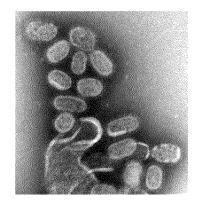
FOIA Confidential Treatment Requested by Theranos

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TS-0325155



H1N1 Assay (Specificity)

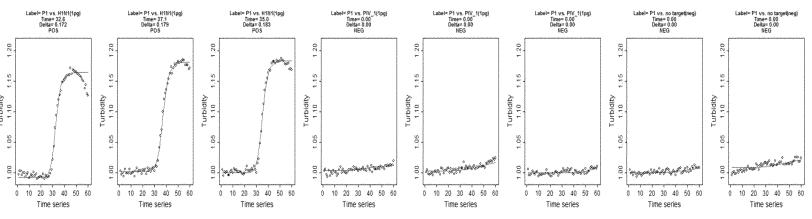


	H1N1 Ass	ay Results
	H1N1 Positive	H1N1 Negative
H1N1 sample	100% (60/60)	0% (32/32)
Cross-reactivity (24 species)	0% (0/96)	100% (96/96)

H1N1 assay with H1N1 sample

H1N1 assay with PIV sample

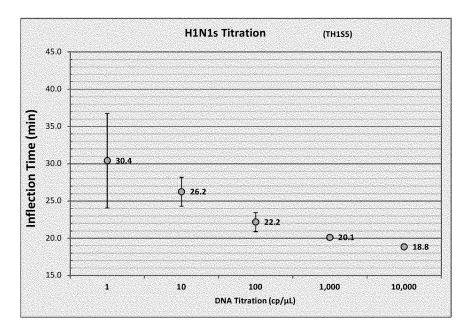
H1N1 assay with no sample





H1N1 Assay (Sensitivity)

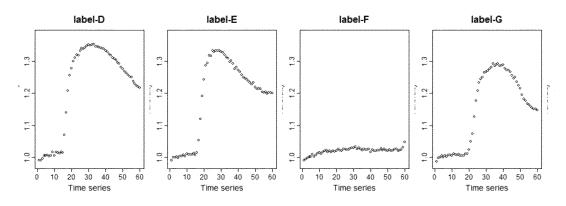
Inflection Time	e (min)
Mean	SD (1)
No Amp	nď
19.9	0.3
18.8	0.1
20.1	0.1
22.2	1.3
26.2	2.0
30.4	6.4
	Mean No Amp 19.9 18.8 20.1 22.2 26.2



H3N2 Brisbane strain (inactivated virus)

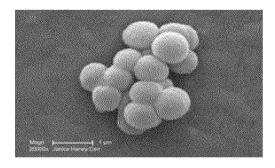


H3N2 assay with H3N2 sample Negative Control Positive Control





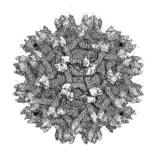
Strep A (inactivated bacteria)



Strep A Assay

Performance Test	Mean	
Negative	No Amp	
Extract (cp/µL)	(min)	
800	24.0	
80	28.3	
8	40.7	

Dengue Virus (RNA extracts)



		Dengue Assay Results			
		Dengue 1	Dengue 2	Dengue 3	
	Dengue 1	Positive 100% (24/24)	Negative 100% (16/16)	Negative 100% (16/16)	
Sample	Dengue 2	Negative 100% (16/16)	Positive 100% (24/24)	Negative 100% (16/16)	
	Dengue 3	Negative 100% (16/16)	Negative 100% (16/16)	Positive 100% (24/24)	

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Theranos Dengue Assays Testing with Synthetic RNA Targets

Theranos primers were verified to perform well against intended pathogen Dengue targets with no cross reactivity.

Theranos Dengue assays detect Dengue 1, 2, 3 and 4 with good specificity.

Dengue Amplification/Cross Reactivity Table at 10K copies/uL

Dengue	Assay 1	Assay 2	Assay 3	Assay 4
Sample 1	Yes	No	No	No
Sample 2	No	Yes	No	No
Sample 3	No	No	Yes	No
Sample 4	No	No	No	Yes